K120065

A107

PLAXTRON INDUSTRIAL (M) SDN. BHD.

APR - 3 2012

510 (K) Summary

5.1 Device Trade Name: Plaxtron Suction Unit, Model 88AA51/88AA61 series

5.2 Named and Address of Manufacturer:
PLAXTRON INDUSTRIAL (M) SDN. BHD.
plot 28, kawasan perusahaan, jelapang 2, ftz,
ipoh, MALAYSIA 30020

Establishment Registration Number: 8044169

Contact Person:
Doris Yang
Engineering / Regulatory Affairs Manager

Or

Leo Chien
General Manager

Tel: 886-2-26892001
Fax: 886-2-26892468
E-mail: chtwn@ms21.hinet.net

5.3 Device Classification Names: 1) apparatus, suction, ward use, portable, ac-powered

Regulation Description: Powered Suction Pump

Review Panel: General & Plastic Surgery,

Regulation Number: §878.4780

Classification: Class II

Product Code: 1) JCX

Recognized Performance Standard ISO 10079-1:2009 (JCX)

5.4 Predicate Devices:

(a) DeVilbiss Suction Unit, Model 88 00 50 & 88 00 60, marketed name: Laerdal Compact Suction Unit (LCSU 3), 510(k) Number: K982304

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Plaxtron Industrial (M) SDN, BHD
% Sen Mu Technology Co., Ltd
Ming-Yie Jan, Ph.D.
No.15-2, Lane 26, Mincyuan 1st Road
Lingya District, Kaohsiung City
Taiwan 802

APR - 3 2012

Re: K120065
Trade/Device Name: Plaxtron Suction Unit
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: II
Product Code: JCX
Dated: March 13, 2012
Received: March 21, 2012

Dear Dr. Ming-Yie Jan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for use

510(k) Number (if known): K120065

Device Name: Plaxtron Suction Unit

Indications for Use:

The device is to be used to remove fluids from the airway or respiratory support system. The device creates a negative pressure (vacuum) that draws fluids through disposable tubing that is connected to a collection canister. The fluids are trapped in the collection canister for proper disposal. It is for use only on the order of a physician or other licensed practitioner (e.g. EMT-field use).

Prescription Use X
(Per 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use_____
(Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Richard P. Fulton for Ned Ogden

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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